

REMARKS:

Claims 1-3 and 6-20 are pending. New claims 21 and 22 have been added. Thus, 20 claims are pending, of which three are independent.

Claims 1, 2, 3, 5, and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield (US Patent No. 4,765,325); claims 6 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of DuBois (US Patent No. 3,948,589); claims 7 and 9-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of Zocca et al. (US Patent Publication 2003/0172925) and Spinello (US Patent Publication 2003/0100888); and claims 18-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of Zocca et al. (US Patent Publication 2003/0172925). All rejections rely on the Crutchfield reference.

Crutchfield describes a method and apparatus for determining respirator face mask fit that involves measuring mask leakage with a flow meter after a test subject exhales most of the air from his lungs, holds his breath, and the air valve (i.e., breathing port) through which the test subject breathes is closed. See Col. 8, lines 53-55. Then, a vacuum source is used to create a chosen negative pressure (Col. 8, lines 59-63).

In the arguments especially on page 8 of the Office Action, the Examiner contends that the Declaration and remarks previously presented by the Applicant were unpersuasive because the Examiner believes that the mask interior will be at ambient pressure prior to the breathing port being closed *at least some of the time* by chance, even though Crutchfield does not explicitly disclose or suggest initiating the fit test protocol after there is ambient pressure in the mask.

Nonetheless, the Applicant has clarified the independent claims to reflect that the fit testing protocol is initiated only after intra-respirator pressure is confirmed to be at substantially ambient pressure. Thus, for example, claim 1 recites in relevant part:

(c) activating a switch that closes a breathing port of said respirator, thereby initiating a controlled negative pressure testing protocol, after monitoring of when intra-respirator pressure indicates said intra-respirator pressure substantially equals ambient pressure;

The basis for these claim amendments, as well as new independent claim 21, is found, e.g., in the last paragraph on page 17 of the published PCT application:

...CNP device monitoring of internal mask pressure to ensure that post-inhalation in-mask pressure returns to ambient pressure before the breathing port is closed;

Nowhere does the Crutchfield reference disclose or suggest monitoring intra-respirator pressure such that that the breathing port is not closed, thereby initiating the testing protocol, until substantially ambient pressure is achieved therein. Moreover, there is no evidence of record that discloses or suggests, in effect, delaying initiation of the fit testing protocol until the monitored intra-respirator pressure is substantially ambient, as claimed.

In contrast to the disclosure of the subject application, which is specifically aimed at overcoming the problem of "imprecise breath holding" as described at page 17 of the published PCT application, there is no disclosure in the Crutchfield reference that teaches or suggests a respirator fit-testing protocol in which ambient pressure inside the mask is confirmed through monitoring prior to closing the breathing valve and initiating the fit testing as claimed in the subject application (see also the previously provided DECLARATION BY Clifton D. Crutchfield, Ph.D., paragraph 8). Thus, claim 1 presents a non-obvious improvement over prior fit-testing protocols because at least all elements of step (c) are not disclosed or suggested by Crutchfield, either alone or in combination with the other cited art.

Similarly, the apparatus claim 17 and new claim 21 include a recitation that substantially tracks the language of claim 1 (e.g., "wherein activation of the switch closes said breathing port of said respirator and initiates a controlled negative pressure testing protocol after monitoring of intra-respirator pressure indicates said intra-respirator pressure substantially equals ambient pressure"). Consequently, these claims also cannot be rendered obvious by Crutchfield or/and the remaining cited art. Moreover, as all other claims depend from either claims 1, 17 or 21, these claims likewise are not obvious.

Claim 2 (and new claim 22) recite "wherein the test subject inhales immediately before holding his breath." Basis for these claims is found, e.g., at page 17 of the published PCT application:

For example, if the test subject prematurely squeezes the bulb before fully completing the "preparatory" inhalation immediately preceding the breath hold, a substantial amount of negative pressure can be trapped inside the respirator, thereby disrupting the initiation and successful completion of air flow measurements.

In contrast to claims 2 and 22, the Crutchfield reference only discloses exhaling immediately prior to closure of the breathing valve.

In view of the foregoing, the applicant respectfully submits that the claims are distinguishable from the cited art, and, thus, present patentable subject matter.

No fee is believed to be due with this response. Please charge any unforeseen costs to our Deposit Account No. 17-0055.

Respectfully submitted,

Quarles & Brady, LLP

/Gavin J. Milczarek-Desai/

Gavin J. Milczarek-Desai
Reg. No. 45,801

520-770-8716 Phone
520-770-2235 Fax